The COI Committee may require that data management and analysis involve input or review by a non-conflicted qualified individual.

**Why this requirement?**

To promote objectivity and transparency in Duke research by minimizing the chance that bias – actual or perceived – is introduced into the conduct of research when financial interests are involved.

**What is meant by data management?**

Data management typically includes the processing steps used to transform raw data into a file suitable for analysis.

**What is meant by data analysis?**

Data analysis might include the review, interpretation or summation of data (findings from experiments, test results, etc.) for purposes of guiding future research, and/or for sharing results (e.g., presentations, publications, grant applications) and statistical analysis.

**What constitutes a non-conflicted individual?**

In general, an individual who qualifies as “non-conflicted” as used in this guidance:

- Does not have any financial interests in the same entity for which the COI management plan has been put in place; AND
- Does not report, in his/her employment at Duke, to someone with financial interests in that entity; AND
- Has appropriate knowledge/expertise to contribute to the data analysis.

Some examples of individuals that typically serve in this role:

- A colleague at Duke, whether or not funded by the same monies that support the research being managed by the COI management plan.
- A colleague outside of Duke, whether or not funded by the same monies that support the research.
- A statistician.
- A colleague who critically reviews the manuscript for a publication or presentation and who has access to the raw data and procedures by which data/samples were collected.
Other proposals for meeting this requirement shall be discussed with the COI Committee or Chair prior to implementation and may be considered as acceptable on a case-by-case basis.

*What are the underlying principles?*

All research should be transparent and rigorous, and this is particularly true when this research is performed by investigators with a financial interest in the results. The data management should effectively include an auditable trail where changes to the database are logged and justified. The data analysis should be reproducible and statistically robust. Although the level of detail will differ from application to application, in general the analysis plan should be pre-specified as this should, among others, reduce concerns regarding selective reporting.